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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,344	10/15/2003	Ivan Osorio	011738.00149	7817

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EXAMINER	
RAJAN, KAI	
ART UNIT	**PAPER NUMBER**
3769	

MAIL DATE	DELIVERY MODE
01/31/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,344	OSORIO ET AL.	
	Examiner	Art Unit	
	Kai Rajan	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11,12 and 14-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,12 and 14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 November 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/2/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the response and amendment filed November 2, 2010.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 8, 11, 12, and 14 - 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw et al. U.S. Patent No. 6,014,587.

1. A method for performing trial screening with a medical device system, the medical device system providing treatment to a patient with a nervous system disorder, the method comprising:

(a) receiving a first input into at least one processor relating to a location of treatment therapy delivery (Column 29 lines 39 - 42, column 30 lines 35 - 37, pulse parameters input into the system); (b) receiving a second input into the at least one processor about a set of therapy

parameters that is associated with a treatment therapy (Column 29 lines 39 – 42, column 30 lines 35 – 37 input of pulse parameters); (c) administering a treatment therapy by the at least one processor in accordance with the first and second inputs (Column 4 lines 19 – 26 stimulation pulses are administered to the patient); and (d) receiving a first indication at the at least one processor whether the treatment therapy is within a range of safety and a second indication at the at least one processor whether to utilize the first and second inputs, wherein the second indication is determined by evaluating a criterion, wherein the criterion is selected from a group consisting of a detection frequency of the neurological event, a duration of the neurological event, an intensity of the neurological event, and an electrographic spread of the neurological event (Column 29 lines 41 – 49, 30 lines 20 -25, lines 31 – 40 comparing pulse width to specified pulse width to determine if it is within a range of safety or tolerance, and determining whether current and voltages are within acceptable ranges. Furthermore, level and magnitude of seizures is measured and monitored for determining the appropriate treatment required).

2. The method of claim 1, further comprising:

(e) if the first indication indicates that the treatment therapy is within a range of safety and if the second indication indicates that the first and second inputs are to be used, applying the treatment therapy at a future point in time (Column 7 lines 26 – 40 signals administered within safety ranges are stored and re-administered to the patient).

3. The method of claim 1, wherein the nervous system disorder is selected from the group consisting of a disorder of a central nervous system, a disorder of a peripheral nervous system, a

mental health disorder, and a psychiatric disorder (Column 1 lines 49 – 67 the system is used to treat nervous system disorders that affect mood and anxiety).

4. The method of claim 3, wherein the nervous system disorder is selected from the group consisting of epilepsy, Parkinson's disease, essential tremor, dystonia, multiple sclerosis (MS), anxiety, a mood disorder, a sleep disorder, obesity, and anorexia (Column 1 lines 49 – 67 stimulation is used to treat disorders that affect at least mood and anxiety).

5. The method of claim 1, wherein the treatment therapy is selected from the group consisting of electrical stimulation, magnetic stimulation, drug infusion, and brain temperature control (Column 1 lines 49 – 67 ECT stimulation).

6. The method of claim 1, wherein the treatment therapy is provided to a location of a body selected from the group consisting of a brain, a vagal nerve, a spinal cord, and a peripheral nerve (Column 1 lines 49 – 67 treatment of the nervous system affects at least the spinal cord, vagal nerve, or peripheral nerve since all nerves fall into these types).

7. The method of claim 1, wherein the medical device system is selected from the group consisting of an external system, a hybrid system, and an implanted system (Column 6 lines 44 – 67, column 7 lines 1 – 56 external system applying stimulation).

8. The method of claim 2, further comprising:

(f) in response to step (e), if the treatment therapy is not successful, repeating steps (a)-(d) (Column 4 lines 50 – 65, column 29 lines 41 – 49 treatment is applied until an unsafe condition is detected, followed by modification of the treatment parameters).

11. The method of claim 1, wherein the evaluating in (d) comprises:

(i) obtaining treatment data during the trial screening session, wherein the treatment therapy is applied (Column 29 lines 39 – 42, column 30 lines 35 – 37 treatment pulse parameters input); (ii) obtaining comparison data during a neurological event screening session, wherein the treatment therapy is not applied (Column 30 lines 20 – 23, lines 37 – 40 data regarding acceptable tolerances and safety ranges are generated and stored), and wherein the comparison data correspond to the treatment data; (iii) deleting a portion of the comparison data corresponding to a blanking interval of the treatment therapy; and (iv) calculating a difference between the treatment data and the comparison data in order to determine the efficacy of the treatment therapy (Column 29 lines 39 – 42, column 30 lines 20 – 23, 37 – 40 treatment parameters are compared to tolerances and safety ranges, where out of safety range data results in termination of the treatment).

12. A non-transitory computer-readable medium having computer-executable instructions for performing the steps recited in claim 1 (Column 7 lines 26 – 56 computer system performs monitoring and stimulation functions).

Claims 14 – 23 are rejected on substantially the same basis as claims 1 – 8, 11, and 12 above, by Shaw et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is (571)272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kai Rajan/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769

January 26, 2011